

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

# PCT

To:

see form PCT/ISA/220

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2004/002866

International filing date (day/month/year)  
02.07.2004

Priority date (day/month/year)  
04.07.2003

International Patent Classification (IPC) or both national classification and IPC  
A61K35/74

Applicant  
NORFERM DA

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITYInternational application No.  
PCT/GB2004/002866

IAP20 Rec'd PCT/PTO 03 JAN 2006

## Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
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**Box No. II Priority**

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1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2004/002866

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 9 (industrial applicability); 1-6, 8-10, 12-15 (all partially); 16-17 (completely)

because:

- ☒ the said international application, or the said claims Nos. 9 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (*specify*):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 1-6, 8-10, 12-15 (all partially); 16-17 (completely)
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- |                            |  |
|----------------------------|--|
| the written form           | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished            |
|                            | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

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**Box No. IV Lack of unity of invention**

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1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ not paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
  - ☐ the parts relating to claims Nos.

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-11, 13-15
	No: Claims	12
Inventive step (IS)	Yes: Claims	1-11, 13
	No: Claims	12, 14, 15
Industrial applicability (IA)	Yes: Claims	1-8, 10-15
	No: Claims	

2. Citations and explanations

**see separate sheet**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2004/002866

**IAP20 Rec'd PCT/PTO 03 JAN 2006**

1. Reference is made to the following documents:

- D1: GB-A-1 319 114 (1973-06-06)
- D2: WO-A-01/49277 (2001-07-12)
- D3: EP-A-0 404 300 (1990-12-27)
- D4: DATABASE MEDLINE [Online] US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; November 1975 (1975-11), WEAVER T L ET AL: "Whole-cell and membrane lipids of the methylotrophic bacterium *Methylosinus trichosporium*." XP002302098 Database accession no. NLM810477
- D5: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1991, BOWAN J P ET AL: "PHOSPHOLIPID FATTY ACID AND LIPOPOLYSACCHARIDE FATTY ACID SIGNATURE LIPIDS IN METHANE-UTILIZING BACTERIA" XP002302099 Database accession no. PREV199191111571
- D6: DATABASE BIOSIS [Online] BIOSCIENCES INFORMATION SERVICE, PHILADELPHIA, PA, US; 1993, PELTOLA PETRI ET AL: "Effect of copper on membrane lipids and on methane monooxygenase activity of *Methylococcus capsulatus* (Bath)" XP002302100 Database accession no. PREV199396092064
- D7: WO 01/60974 A (LARSEN JAN ; GOLDING LOUISE (GB); JOHANNESSEN ARILD (NO); KLEPPE GUNNA) 23 August 2001 (2001-08-23)

**Re Item IV**

**Lack of unity of invention**

2. In line with the objection raised in the search report, the international preliminary examining authority is of the opinion that the present application (-with the claims presently on file-) does not comply with the requirements of unity of invention as set forth in Rule 13.1 PCT, for the following reasons:

2.1 **Present claims 1-17 are directed to**

- (1) medicaments comprising microbial lipids [claims 10, 11, 12 (part), 13, 15 (part)] and the use of said medicaments for reducing plasma cholesterol or the ratio LDL/HDL in plasma [claims 1, 4-8 (part), 9];
- (2) medicaments comprising microbial lipids [claims 10, 11, 12 (part), 13, 15 (part)]

and the use of said medicaments for increasing plasma DHA (docosa-hexaenoic acid) [claims 2, 4-8 (part)];

- (3) medicaments comprising microbial lipids [claims 10, 11, 12 (part), 13, 15 (part)] and the use of said medicaments as immuno-protectant agents [claims 3, 4-8 (part)];
- (4) foodstuff comprising microbial lipids [claims 14, 15 (part)];
- (5) food products harvested from animals fed with a microbial lipid [claims 16-17].

3. The common concept linking the aforementioned five different aspects of the claimed subject matter is "microbial lipids and their use as food or medicine"

3.1 Said concept is neither new nor inventive, because compositions (for medical or dietary use) comprising microbial lipids are already known from the state of the art see e.g. D1 to D3 below.

**D1** (see e.g. claims 1, 4 and 8 in conjunction with c. 2, l. 9-11) discloses a method for preparing microbial lipids, including phospholipids, and their use as food or for medicine.

**D2** (see e.g. claims 1, 8 or 11 and examples 1-3) discloses bacterial lipids, including phospholipids, as well as their use in medicine for increasing immune effects and their use as food additive.

**D3** (see e.g. claims 1, 7, 10, 14, in conjunction with p. 4, l. 27-29 and Table 4) discloses bacterial lipids, including phospholipids such as phosphatidylethanolamine, their therapeutic use for reducing cholesterol, and their use as animal feed, e.g. as chicken feed to produce low-cholesterol eggs.

3.2 Thus, each of the five different aspects of the claims specified above (see point 2.1) is considered to relate to a separate invention or groups of inventions which are not so linked as to form a single inventive concept.

4. Although the claimed subject matter does not comply with the requirements of

unity of invention, due to the objections under Art. 5-6 PCT raised below, this authority has chosen, according to rule 68.1 PCT, not to invite the applicant to restrict the claims or to pay additional fees.

**Re Item III.**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

5. **Claim 9** relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).
6. Independent **claims 1, 2, 3, 9, 10, 12, 14, 15 and 16** lack clarity and support of disclosure within the meaning of Article 5 and 6 PCT because scope of the features "*microbial lipid(s)*" or "*microbial lipid extract*" used in said claims is not supported by the technical contents of the application. Indeed, said features encompass lipids from an extremely large number of microorganisms (including bacteria, yeast or fungi), whereas the application (see in particular examples 1-2) provides support within the meaning of Article 6 EPC and/or disclosure within the meaning of Article 5 EPC for only a very limited number bacteria, namely methanotrophic bacteria. The same applies to the dependent **claims 4-6, 8, 13 and 17**.  
Furthermore, the application provides no support any particular technical feature of food products as claimed in present **claims 16-17**.
- 6.1 In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole breadth of the features "*microbial lipid(s)*" or "*microbial lipid extract*" and over the products according to claims 16 and 17 is impossible.  
Consequently, **the search** has been carried out as if the aforementioned unclear features "*microbial lipid(s)*" or "*microbial lipid extract*" in claims 1-6, 8-10, and 12-15 had been **restricted to "lipids of lipid extracts from methanotrophic bacteria"**. **Claims 16-17** have **not** been **searched** at all.
7. According to Rule 66.1(e) PCT, no international preliminary examination will be carried out in respect of the subject matter which is not covered by the search



report.

7.1 Thus, for the purpose of this report, **claims 1-15 had been read as if they were restricted to "*lipids of lipid extracts from methanotrophic bacteria*".**

7.2 For **claims 16-17 no opinion** will be established.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**Novelty**

8. The subject matter of **claim 12 is not new** because lipids from methanotrophic bacteria, including lipids from *Methylococcus* are already known from the state of the art; see e.g. **D4-D6**.

Claim 12 does therefore not meet the requirements of Art. 33(2) PCT.

9. The remaining **claims 1-11 and 13-15** meet the requirements of Art. 33(2) PCT because their subject matter is formally new over the prior art cited in the search report.

**Inventive step**

10. **Claims 14 and 15 (in part)** do not meet the requirements of Art. 33(3) PCT for the reasons set out below.

10.1 D7 (see e.g. claims 17-19 in conjunction with p. 13, l. 5-8) discloses a food grade product for human and/or animal consume, said product being a homogenised single-cell protein material obtained from the methanotrophic bacterium *Methylococcus capsulatus*. As indicated in D7 (see e.g. p. 10, l. 1.6) said product also comprises from 5 to 20 % fat (i.e. lipids).

10.2 In view of the known suitability of cellular material from methanotrophic bacteria for human/animal consume, wherein said material contains lipids (see D7 above), those skilled in the art aware of the teachings of D4-D6, would have found it obvious to prepare and use pure lipid or lipids extracts from methanotrophic bacteria with the aim of producing food or nutraceutical products for human/animal consume.

10.3 Thus, no inventive step can be recognised for the subject matter of claim 14 and 15 (in part) in view of the teachings of D7 in combination with any of D4 to D6.

11. **Claims 1-11, 13 and 15 (in part)** meet the requirements of Art. 33(3) PCT because none of the documents cited in the search report teaches or suggests any possible medical use of lipids from methanotrophic bacteria.

**Industrial applicability:**

12. Claims 1-8, 10-15 satisfy the criterion set forth in Art. 33(4) PCT because their subject matter is susceptible of industrial application.